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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,908	07/21/2003	Paul John Kawula	50623.245	5357
<div>Charles E. Runyan⁷⁵⁹⁰ Squire, Sanders & Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111</div>				
EXAMINER				
PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
05/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/623,908

Applicant(s)

KAWULA, PAUL JOHN

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-29 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 22, 23, 27-29 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/19/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites the limitation "the first porous region" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,22,23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cremascoli (4813959). Fig. 1 shows a medical device (1) for implanting in a patient. It can be seen that the device has an attachment region within in the form of an indentation in the outer surface and has a porous ceramic region (6) disposed therein and a second less porous ceramic region (5). Cremascoli discloses the material is ceramic, col. 2, lines 5-8,19. The device is made of metal, such as stainless steel (col. 1, line 63, col. 2, lines 34,35) and comprises the ceramic components.

Claims 6-8,22,23,27,29,47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Gayer et al. (6461385). Gayer et al. disclose a medical device formed of wires, col. 5, lines 34,40. Gayer also discloses the wires are made of metal such as titanium, stainless steel or gold, col. 7, lines 49,50. Fig. 1 shows the implant body surface **104** having attachment regions in the form of indentations **106**. Fig. 5 shows the process of coating the device **400** where the surface is coated with an oxide layer **402**. Regarding claim 48, the oxide layer is of the material that the body is comprised, col. 9, lines 54-56. With respect to claim 49, Gayer discloses removing some of the material to form attachment regions, col. 7, lines 33-35. Gayer then discloses to coat the oxide layer with a ceramic **404** as seen in Fig. 6, col. 10, line 20. Then the ceramic layer has a porous layer or side placed thereon **406** as seen in Fig. 7. Gayer discloses the porous side has ceramic disposed therein, col. 10, lines 42,49. With respect to claims 7,8,29, Gayer discloses the porous region has a drug, such as an anti-inflammatory, col. 5, lines 49,51,55,56.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cremascoli '959 in view of Alt (60999561). Cremascoli is explained supra. However, Cremascoli fails to disclose the use of a drug with ceramic implants. Alt teaches that drugs are commonly used with ceramic coated implants to make the device more biocompatible by using an anti-inflammatory, col. 10, lines 42-61. It would have been obvious to one of ordinary skill in the art to incorporate an anti-inflammatory drug in the porous ceramic as taught by Alt with the medical device of Cremascoli such that it reduces inflammation at the site of implantation to permit the device to be used.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gayer et al. '385 in view of Ding et al. (2002/91433) or Yan (6240616). Gayer et al. is explained supra. However, Gayer et al. fail to disclose the medical implant can be a stent. It is well known in the art that wires are used to form stents and also include coatings as disclosed by Gayer to be used in the vascular system. Both Ding et al. and Yan teach stents are made from metal wires and that the stent is coated with a drug. It would have been obvious to one of ordinary skill in the art to use the coated drug wires of Gayer et al. and form a stent as taught by Ding or Yan since the therapeutic wires are biocompatible and capable of supporting a vessel by forming a stent disclosed in Ding or Yan.

Response to Arguments

Applicant's arguments with respect to claims 1,27 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738